



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|---|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/562,469 | 05/31/2006 | Masato Miyake | 690121.405USPC | 8185 |
| 500 | 7590 | 03/18/2009 | EXAMINER | |
| SEED INTELLECTUAL PROPERTY LAW GROUP PLLC | | | BRUSCA, JOHN S | |
| 701 FIFTH AVE | | | ART UNIT | PAPER NUMBER |
| SUITE 5400 | | | | |
| SEATTLE, WA 98104 | | | 1631 | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/18/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 10/562,469 | Applicant(s) MIYAKE, MASATO |
| | Examiner John S. Brusca | Art Unit 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 January 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-144 is/are pending in the application.
 4a) Of the above claim(s) 1-127 and 144 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 128-143 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 22 December 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 5/31/2006
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. The filing receipt for the instant application listed only Masato Miyake as an applicant and did not list Tomohiro Yoshikawa or Jun Miyake. A revised filing receipt will be sent to the applicants under separate cover listing all three applicants indicated on the Application Data Sheet filed 22 December 2005.

Status of the Claims

2. Claims 1-144 are pending.

Claims 1-127 and 144 are withdrawn

Claims 128-143 are rejected.

Election/Restrictions

3. Applicant's election of Group 6 in the reply filed on 15 January 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 1-127 and 144 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 January 2009.

Information Disclosure Statement

5. The information disclosure statement filed 31 May 2006 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. References

AL (WO 99/60094) and AO (WO 02/07100) have not been considered. The remaining cited references have been considered as noted in the attached signed list of references.

Specification

6. The disclosure is objected to because of the following informalities: On pages 163-166 and 169 the formulas on the pages overlay and obscure text of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 128-132, 134, and 135 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 128-132, 134, and 135 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. The claimed subject matter is a method of gathering data of cell assays to construct digital cell database. In some embodiments requests for data from the electronic cell are processed. The claimed subject matter does not have a limitation that the operations of the claimed process are done on a computer. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory

Art Unit: 1631

subject matter (In re Grams 12 USPQ2d 1824 Fed. Cir. 1989). Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. The applicants are cautioned against introduction of new matter in an amendment.

9. Claims 128-133 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

For a process that comprises an abstract idea to be statutory, it must comprise a practical application of the abstract idea. Claimed subject matter may require a practical application by claiming, or requiring use of, a machine, or by requiring a physical transformation of an article to a different state or thing (In Re Bilski (88 USPQ2d 1385 Fed. Cir. 2008). Even if claimed subject matter claims, or requires use of, a machine, the claimed subject matter may not require a practical application. One indication that claimed subject matter requires a practical application is an explicit requirement of a useful concrete, and tangible result as discussed in In re Alappat (31 USPQ2d 1545 Fed. Cir. 1994)

Although many, or arguably even all,²² of the means elements recited in claim 15 represent circuitry elements that perform mathematical calculations, which is essentially true of all digital electrical circuits, the claimed invention as a whole is directed to a combination of interrelated elements which combine to form a machine for converting discrete waveform data samples into anti-aliased pixel illumination intensity data to be displayed on a display means.²³ This is not a disembodied mathematical concept which may be characterized as an “abstract idea,” but rather a specific machine to produce a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be “useful” the claim must produce a result that is specific and substantial. For a claim to be “concrete” the

process must have a result that is reproducible. For a claim to be “tangible” the process must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 128-133 do not require production of a tangible result in a form that is understandable to the user of the process or apparatus. The claimed subject matter gathers data of cell assays but does not require that the data is outputted in a user interpretable form. The data is only limited to be produced but is not required to be stored in a database or otherwise provided to a user. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the process is outputted to a physical memory device, a display, to a user, in a graphical format, or in a user readable format, or by including a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 128-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rine et al. (WO 98/06874, reference AK in the Information Disclosure Statement filed 31 May 2006).

The claimed subject matter is a process of obtaining data of a cell type, culture medium, chemical stimulus and reporter output, and recording the data in a database. In some embodiments the process is performed on a plurality of cell cultures or the claimed subject matter is an apparatus that executes the process.

Rine et al. shows in the abstract a process and apparatus that collects data of a plurality of cells. The signals are that of a reporter in response to a stimulation. The signals of the cells are stored in a database. The process and apparatus are further discussed on pages 2 and 4. Rine et al. shows on page 4 that the stimulus can be a pharmacological agent. Figure 1 shows a database of the stored profile results, and an apparatus that executes the process. Rine et al. shows use of the database for comparison queries on page 7. On page 5, Rine et al. shows adjustment of incubation conditions to avoid stress. Rine et al. shows a working example using yeast cells with lacZ fusion reporters on pages 8-17, and is further exemplified on pages 17-19 using different stimuli. Basal response determination is recorded on page 15 which is taken at a particular physical condition of temperature, pH, incubation medium, and osmolarity. Comparison of response profiles are shown on page 16.

Rine et al. does not explicitly show recording cell type, stimulus, or cell culture medium.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include in the recorded profile data of Rine et al. the data of the

Art Unit: 1631

experimental cell type, culture medium, and stimulus to aid in comparison to other profiles because Rine et al. shows comparison of the determined profiles with other profiles and knowing what the cell type, culture, and stimulus is essential to comparison of the stimulus results with other stimulus results.

12. Claims 134-137, 140, and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rine et al. as applied to claims 128-133 above, and further in view of Rosenblum (U.S. Patent Application Publication No. 2002/0055935).

The claimed subject matter is a process of obtaining data of a cell type, culture medium, chemical stimulus and reporter output, and recording the data in a database, receiving a request for a comparison search with a profile of a requester with the profiles in the database, searching the database, and providing the result of the search to the service requester. In some embodiments the process is performed on a plurality of cell cultures to form a plurality of database, a plurality of database sources are considered for the search, the requester requests the comparison via the Internet, or the claimed subject matter is an apparatus that executes the process.

Rine et al. as applied to claims 128-133 above does not show comparison initiated by a requester, consideration of multiple databases for the comparison, provision of the results of the comparison to the requester, or requesting of a comparison via the Internet.

Rosenblum shows in the abstract and figure 1 an apparatus that queries a database via the Internet. Rosenblum shows in paragraph 10 use of a database of therapeutic agents that is queried by the Internet. Rosenblum shows in paragraph 13 that multiple databases containing profiles may be queried, and data subsets in paragraph 16 of research data pertaining to the agent.

Rosenblum shows selection from among multiple databases in paragraph 21. Rosenblum shows types of data in the profiles in paragraph 38 that include results of assays such as effects of agents on a variety of cell components.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the process and apparatus of Rine et al. by use of the biological database query method and apparatus of Rosenblum because Rosenblum shows how access to biological databases by requester may be performed conveniently via the Internet.

13. Claims 138, 139, 142 and 143 rejected under 35 U.S.C. 103(a) as being unpatentable over Rine et al. in view of Rosenblum as applied to claims 134-137, 140, and 141 above, and further in view of Bimson et al. (U.S. Patent Application Publication No. 2001/0034748).

The claimed subject matter is an apparatus that executes a process of obtaining data of a cell type, culture medium, chemical stimulus and reporter output, and recording the data in a database, receiving a request for a comparison search with a profile of a requester with the profiles in the database, searching the database, and providing the result of the search to the service requester using a format in the extensible markup language (XML).

Rine et al. in view of Rosenblum as applied to claims 134-137, 140, and 141 above do not show output in XML format.

Bimson et al. shows in the abstract a process of searching a database and providing the results of the search in XML format. Bimson et al. shows hardware that executes the process in paragraphs 12, 14, and 15.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use XML format to output the search results of Rine et al. in view of

Rosenblum as applied to claims 134-137, 140, and 141 above because Bimson et al. shows use of XML formats as a known and useful format for search results.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 128-133 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 82, 84-87, and 90 of copending Application No. 11/630814. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of making a digital cell database of the copending claims comprises the same steps as the instant claimed method of making a digital cell.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/
Primary Examiner, Art Unit 1631

jsb